

GERALD K. WHITE & ASSOCIATES, P.C.205 West Randolph Street, Suite 835
Chicago, Illinois 60606Telephone (312) 920-0588 • Fax (312) 920-0580
E-mail: gkwpatlaw@aol.com**RECEIVED
CENTRAL FAX CENTER****FEB 21 2006****ASSOCIATES**

Charles N. Lovell, Esq.* - Patents

Henry W. Tarring, Esq.* - Patents

*Member of Virginia Bar

BUSINESS ASSOCIATE

Karen D. Allen • Trademarks

FACSIMILE COVER SHEET

DATE: February 21, 2006 **NO. OF PAGES:** 16

TO: Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: Examiner Elizabeth Kemmerer, Ph.D.
Art Unit 1646

FAX NO.: (571) 273-8300

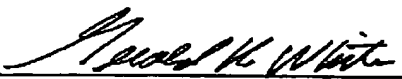
FROM: Gerald K. White

RE: Patent Application Serial No. 09/064,000
Applicant: James P. Elia
Filed: April 21, 1998
Title: METHOD AND APPARATUS FOR
INSTALLATION OF DENTAL IMPLANT

Sir:

Enclosed is Applicant's **Sixth Supplemental Information Disclosure Statement** (including Certification), Form PTO-1449 (Modified), and a copy of the publication listed thereon (Reference ACA).

Respectfully submitted,


Gerald K. White
Reg. No. 26,611
Attorney for Applicant**CONFIDENTIALITY WARNING**

The accompanying facsimile transmission is a confidential communication that is legally privileged. If you are not the intended recipient, please notify the sender immediately at the number listed above. Thank you.

PATENT
Appl. No. 09/064,000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED
CENTRAL FAX CENTER**FEB 21 2006**

In Re Application of: James P. Elia)

Serial No.: 09/064,000)

Filed: April 21, 1998)

For: METHOD AND APPARATUS)
FOR INSTALLATION OF)
DENTAL IMPLANT)

Group Art Unit: 1646

Examiner: Elizabeth Kemmerer, Ph.D.

SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**MAIL STOP NON-FEE AMENDMENT**Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

Sir:

Enclosed herewith, please find Form PTO-1449 (Modified) pertaining to the above-identified application. A copy of the publication listed thereon (Reference ACA) is enclosed.

This Sixth Information Disclosure Statement (hereinafter "IDS") is submitted to further address the indefiniteness issue raised by the Examiner under 35 U.S.C. §112, second paragraph, regarding the meaning of the terms "multifactorial" and "nonspecific cells." While Applicant believes that such terms are properly used in the instant specification and that one skilled in the art would fully comprehend their meaning in the context of the described and claimed invention, the newly cited publication will further acquaint the Examiner with such terms as they are used in the medical art.

Reference ACA, entitled, "Mesenchymal Stem Cells," authored by Arnold I. Caplan (hereinafter referred to as "Caplan 1991"), is a pre-filing date publication illustrating the art's use of the questioned terminology. Such publication was only recently discovered by Applicant and thus could not have been submitted earlier with the evidence already of record in this application. While

PATENT
Appl. No. 09/064,000

Applicant has previously submitted extensive evidence regarding the meaning of the questioned terminology, Caplan 1991 is particularly relevant because it constitutes the only evidence provided by Applicant that was published prior to Applicant's filing date. Thus, such citation establishes the use and understanding of the terminology by those skilled in the medical art at the time of Applicant's filing date.

Applicant believes that Caplan 1991, like the 2001 Caplan et al. post-filing publication designated as Exhibit H in Applicant's Response to the Final Rejection of October 20, 2005, filed December 2, 2005, contains evidence that those skilled in the medical art understand and use the questioned terms in a manner consistent with Applicant's use thereof; and, consequently, there can be no doubt that these terms are definite within the meaning of 35 U.S.C. § 112, second paragraph. Caplan 1991 described mesenchymal stem cells ("MSC"), which were harvested from bone marrow and/or periosteum, as both multifactorial and non-specific. Specific passages are referenced below in support of Applicant's belief.

Regarding non-specific cells, species of the genus, growth factor, Caplan 1991 disclosed that MSC could develop into nine (9) separate and unique tissues. In this regard, please see Figure 1, page 642.

Regarding Applicant's use of the term "multifactorial cells," which cells are species of the described and claimed genus "growth factor," Caplan 1991 recognized and attributed multifactorial characteristics to MSC at page 641, left column paragraph 1, lines 8-14 and at the top of page summary, lines 6-8.

The first reference at page 641 is as follows:

Their progeny are affected by a number of factors, however, as they become tracked into very specific developmental pathways in which both intrinsic and extrinsic factors combine to control the molecular and cellular pattern of expression that results in specific tissues that perform specific functions based on their molecular repertoire (9,11).

The second reference at page 641 is as follows:

Local cuing (extrinsic factors) and the genomic potential (intrinsic factors) interact at each lineage step to control the rate and characteristic phenotype of the cells of the emerging tissue.

PATENT
Appl. No. 09/064,000

As can be appreciated by the Examiner, more than one (multifactorial) factors are set forth in Caplan 1991.

The Examiner's attention is directed to the fact that parent Application Serial Number 08/326,857 was granted to Dr. Elia on June 2, 1998 as Patent Number 5,759,033 (hereinafter "the '033 patent"). Claims 13 and 26 of the '033 patent specify that the claimed growth factor is multifactorial and non-specific. The grant of such claims, by the Patent and Trademark Office (hereinafter "PTO") constitutes compelling evidence that the definiteness requirements of 35 U.S.C. §112, second paragraph, were satisfied. Applicant submits that the current Examiner's belated questioning of such accepted terminology results in inconsistent prosecution and amounts to a failure to give full faith and credit to the previous action of the PTO. See MPEP 706.04. Unless the Examiner can provide compelling, contradictory evidence, the PTO's earlier action must be maintained.

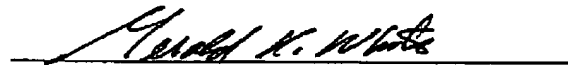
In summary, the rejection under 35 U.S.C. §112, second paragraph for indefiniteness should be favorably reconsidered and withdrawn in view of Applicant's body of evidence that the questioned terminology is accepted, understood, and used by those skilled in the medical art. Moreover, the prior Examiner appears to have also understood and accepted such terminology by granting claims 13 and 26 of the above-mentioned '033 patent.

This IDS is being submitted in an effort to reduce the number of issues in the instant application and thereby expedite the prosecution thereof.

No fee is believed to be due because Applicant and Applicant's attorney were not aware of such reference more than three (3) months prior to this submission. A certification including such facts is enclosed.

Respectfully submitted,

Date: February 21, 2006



Gerald K. White
Reg. No. 26,611

PATENT
Appl. No. 09/064,000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED
CENTRAL FAX CENTER

FEB 21 2006

In Re Application of: James P. Elia)

Serial No.: 09/064,000)

Filed: April 21, 1998)

For: METHOD AND APPARATUS)
FOR INSTALLATION OF)
DENTAL IMPLANT)

Group Art Unit: 1646

Examiner: Elizabeth Kemmerer, Ph.D.

CERTIFICATION

MAIL STOP NON-FEE AMENDMENT

Commissioner for Patents

P.O. Box 1450

Arlington, VA 22313-1450

Sir:

I, Gerald K. White, Attorney for Applicant, hereby state that the reference cited in this Sixth Supplemental Information Disclosure Statement ("IDS") was first discovered by me less than three (3) months prior to the date set forth below.

I further state that no item of information contained in this Sixth Supplemental IDS was cited in a written communication from a foreign patent office in a counterpart foreign application, and, to my knowledge, after making reasonable inquiry, no item of information contained in this Sixth Supplemental IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three (3) months prior to the filing of this statement.

Respectfully submitted,

Date: February 21, 2006Gerald K. White
Reg. No. 26,611

**List of Patents and Publications For
Applicant's 6th Supplemental Information Disclosure Statement**
Page 1 of 1

Form PTO-1449 (Modified)
(Use several sheets if necessary)

Docket No.:

Serial No.: 09/064,000

Group No.:

1646

Filing Date: April 21, 1998

Examiner:

Elizabeth Kemmerer, Ph.D.

Applicant: James P. Elia

Reference Designation U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Sub- Class	Filing Date (if appropriate)

Foreign Patent Documents

		Document Number	Date	Country	Class	Sub- Class	Translation Yes	No

Other Art (including author, title, date, pertinent pages, etc.)

	ACA	Caplan, A.I., "Mesenchymal Stem Cells," <u>Journal of Orthopaedic Research</u> , Vol. 9, No. 5, 1991, pgs. 641-650

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.